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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,195	10/30/2003	Eric M. Leproust	10030416-1	3542

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EXAMINER

SALMON, KATHERINE D

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/698,195

Applicant(s)

LEPROUST ET AL.

Examiner

Katherine Salmon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, 13-15, and 22 drawn to a method of identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe, classified in class 536, subclass 25.3 and in class 435, subclass 6, respectively.
  - II. Claim 11-12, drawn to a computer readable medium, classified in class 702, subclass 19.
  - III. Claim 16, drawn to a nucleic acid array, classified in class 435, subclass 287.2.
  - IV. Claims 17-20, drawn to a method of detecting the presence of a nucleic acid analyte in a sample, classified in class, subclass.
  - V. Claim 21, drawn to kit comprising an algorithm and instructions for use, classified in class 707, subclass 3.
  - VI. Claim 23, drawn to a method of identifying a sequence of a polymeric ligand comprising evaluating a plurality of candidate probe sequences, classified in class 435, subclass 7.1

The inventions are distinct, each from the other because of the following reasons:

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2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention I is drawn to a method of identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe and a method of producing a nucleic acid array with substrate surface immobilized probes and Invention II is drawn to a computer readable medium. The two inventions share a common component wherein the product of the method of Invention I can be used with the product of Invention II. Beyond this commonality, however, Inventions I and II are distinct from one another because they have different modes of operation, different functions, and different effects. For example, a computer readable medium could contain many different data sets besides the ones produced by the method of Invention I.

3. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by the method of identifying a sequence of substrate surface immobilize probes and producing an array or it could be made with a method to produce an array using fragments from known substrate surface immobilized genes.

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4. Inventions I and IV are distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions share a common step where they both are methods involving substrate surface immobilized probes. Beyond this commonality, however, the methods are distinct from one another because they have different goals and would require different additional process steps, reagents, and analyses for their completion.

5. Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of identifying a sequence of a nucleic acid for use as a substrate surface immobilized probe and a kit comprised of an algorithm and instructions for use. The two inventions share a common component wherein both the product and method are drawn to identifying a substrate surface immobilized probe. Beyond this commonality, however, Inventions I and IV are distinct from one another because they have different modes of operation, different functions, and different effects. For example an algorithm could be used to determine many different types of probes besides the ones produced by the method of Invention I.

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6. Inventions I and VI are drawn to distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions share a common step where they both are methods involving substrate surface immobilized probes. Beyond this commonality, however, the methods are distinct from one another because they have different goals and would require different additional process steps, reagents, and analyses for their completion.

7. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a computer readable medium and a nucleic acid array. There is no indication that the product of an array is used with the computer medium and therefore there is no relationship between the two inventions.

8. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention II is drawn to a computer readable medium whereas Invention IV is drawn to a method of detecting the presence of a nucleic acid analyte in a sample. There is no indication that the computer readable medium and the kit comprising an

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algorithm are used together and therefore there is no relationship between the two inventions.

9. Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a computer readable medium and a kit comprised of an algorithm and instructions for use. There is no indication that the kit is used with the computer medium and therefore there is no relationship between the two inventions.

10. Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a computer readable medium and a method of identifying a sequence of a polymeric ligand. There is no indication that the computer readable medium is used in the method of identifying a sequence of a polymeric ligand and therefore there is no relationship between the two inventions.

11. Inventions III and IV are related as product and process of using. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the

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product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be used in a method to detect the presence of a nucleic acid analyte or it could be used in a gene expression study. The search for each invention presents a serious burden, as the searches for each are not coextensive in scope. Art relating to the methods of detecting an nucleic acid would not necessarily provide description information on the array itself, and vice versa.

12. Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to an array and a kit comprised of an algorithm and instructions for use. There is no indication that the kit is used with the array and therefore there is no relationship between the two inventions.

13. Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a nucleic acid array and a method of identifying a sequence of a polymeric ligand. There is no indication that the nucleic acid array is used in the method of identifying a sequence of a polymeric ligand and therefore there is no relationship between the two inventions.



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14. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of detecting the presence of a nucleic acid and a kit comprised of an algorithm and instructions for use. There is no indication that the method of detection uses the kit comprised of an algorithm and therefore there is no relationship between the two inventions.

15. Inventions IV and VI are distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions share a common step where they both are methods involving substrate surface immobilized probes. Beyond this commonality, however, the methods are distinct from one another because they have different goals and would require different additional process steps, reagents, and analyses for their completion.

16. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of identifying a sequence of a polymeric ligand and a kit comprised of an algorithm and instructions for use.

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There is no indication that the method of identifying a sequence of a polymeric ligand uses the kit comprised of an algorithm and therefore there is no relationship between the two inventions.

17. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re

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Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

18. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because Inventions I-V require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restrictions for examination purposes as indicated is proper.

19. A telephone call was made to Bret Field on 2/03/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday -Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Katherine Salmon 2/3/2006*

Katherine Salmon  
Examiner  
Art Unit 1634

*Jehanne Sitton*  
JEHANNE SITTON  
PRIMARY EXAMINER  
*2/6/06*